

# Consent Policy Design Group

## Meeting Minutes

MEETING DATE	MEETING TIME	Location
May 21, 2019	1:00PM – 2:00PM	<b>Join Zoom Meeting:</b> <a href="https://zoom.us/j/269726549">https://zoom.us/j/269726549</a> <b>Dial:</b> +1 646 876 9923 US <b>Meeting ID:</b> 269 726 549

DESIGN GROUP MEMBERS					
Stacy Beck, RN, BSN		Susan Israel, MD	x	Nic Scibelli, MSW	x
Pat Checko, DrPH	x	Rob Rioux, MA			
Carrie Grey, MSIA		Rachel Rudnick, JD	x		
SUPPORTING LEADERSHIP					
Allan Hackney, OHS		Chris Robinson, CedarBridge	x	Tim Pletcher, Velatura	x
Carol Robinson, CedarBridge	x	Ross Martin, CedarBridge	x	Lisa Moon, Velatura	x
Michael Matthews, CedarBridge	x	Sheetal Shah, CedarBridge			

Minutes			
	Topic	Responsible Party	Time
1.	<b>Welcome and Overview</b>	<b>Michael Matthews</b>	<b>1:00 PM</b>
	Michael Matthews welcomed the workgroup members. Michael provided an overview of the agenda and indicated most of the agenda will be led by Velatura.		
2.	<b>Public Comment</b>	<b>Attendees</b>	<b>1:02 PM</b>
	No public comments at this time.		
3.	<b>Design Group Check-in</b>	<b>Attendees</b>	<b>1:05 PM</b>
	<p>Michael Matthews indicated that the meetings to date have been focused on presenting information, but the discussion today and meetings moving forward will be more interactive and have much more participation from the Design Group members. Michael Matthews asked if anyone had comments, questions or issues upfront they want to ensure are addressed.</p> <p>Susan Israel indicated that she is not clear about state regulations or laws regarding data the State receives, such as outpatient discharge summaries or tumor data. She asked if this would automatically go through the HIE, above and beyond consent from the patient. She also asked if there was a distinction made for data related to HIPAA treatment, payment and operations (TPO) without patient consent specifically. Susan Israel understood the information presented by Velatura but wanted to better understand how it would be applied. As an underlying question, she asked how much of the electronic record will go into the HIE without patient consent and what data will be stored. Based on her understanding, NY stores data with limited patient consent. Michael Matthews thanked Susan Israel for her questions. He replied that her questions related to TPO and what data will be stored will be addressed during the discussion today by Velatura. He indicated that they will pick up the discussion related to state regulations and mandated reporting at a future meeting, either meeting 5 or 6.</p>		
4.	<b>Use Case Approach to Sharing Health Data (Part 2)</b>	<b>Velatura</b>	<b>1:55 PM</b>
	Lisa Moon thanked Susan Israel for her comments and questions. She said that these questions align with the use case approach. Each of the examples provided align with separate use cases, as they are based on a legal structure and policy framework in the state. Michael Matthews added that the use cases will drive the types of services provided and the types of data exchanged. As the Use Case Factory (UCF) becomes active, he		

hopes the Consent Design Group will have developed a structure and process so the consent policy and framework to support each use case gets developed at the same time.

Pat Checko mentioned that she is aware of Susan Israel's concern about public health data. However, building off the STD example, people who are required to report to the local health department and to the Department of Public Health (DPH) will still have to report this data. People who have access to this data are still limited to the people within the state and the local health department who have reason to see it. Susan Israel thanked Pat Checko. Susan Israel asked if this data will go through the HIE.

Rachel Rudnick indicated she would also like to think through who will see the data, as there is still a requirement for accounting of disclosures even when it is not consent based. Michael Matthews indicated that they would pick up this question when state-required reporting is discussed.

Lisa Moon provided an overview of this meeting's objectives and hoped the presentation answers some of these questions. Today's objectives included: brief review and question session about prior data sharing concepts; deep dive into the HIPAA Organizing Principle; and to develop a policy position that may be leveraged for statewide consent policy for developing a health information exchange. She provided a reminder on the HIE continuum regarding information exchange. At one end of the continuum is the network-of-networks model. Organizations tend to trust this model more because the HIE does not keep the data. This model is also often less costly, and it is easier to make progress as there are lower expectations and concerns. Lastly, this model is similar to how the internet works and is therefore more "future proof" in a world moving towards a web of interoperable systems. At the other end of the continuum is a longitudinal medical record. In this model, once everyone participates, it simplifies where to go for data. The data is already available for new uses not previously envisioned and there is the ability to conduct advanced analytics.

Susan Israel asked if patients are giving consent when providers send or receive discharge alerts, for their longitudinal health record to be in the HIE, and for conducting advanced analytics. Tim Pletcher said that under HIPAA, providers can disclose information to other providers without additional patient consent, beyond notice of privacy practices. As it related to the alerting question, Tim Pletcher indicated that there is no special consent required for alerting the other covered entity for one of their patients. Susan Israel asked if data under TPO is going to be sent through the HIE without patient consent. Tim Pletcher replied yes, but the data will not be kept in the HIE beyond a convenience threshold to ensure it is delivered. There is a higher bar for longitudinal medical records, and there would be more opportunities for patients to opt out because there are additional secondary uses.

Susan Israel would like to better understand if the vendor would process the information, if the vendor would be a business associate and if they would have access to the data. Tim Pletcher indicated that the vendor would be a business associate. Susan Israel indicated that if a patient does not want a provider to know they were hospitalized for a psychiatric episode, she does not personally think it is okay for this type of disclosure to be made. She asked if there are HIEs where people can opt-out of having all of their data included. Tim Pletcher replied yes. They are taking a use case approach and trying to tackle this one issue at a time. Every single use case, like the tumor registry, needs to describe what is permissible and what is not. Susan Israel asked if this also included alerts and mandatory state reporting. Tim Pletcher indicated these would be treated as separate use cases – each would have their own set of permissible uses which defines where the data is going and how long the data stays in the HIE. Only the participants in the network that have executed a legal exhibit would send information.

Pat Checko mentioned that the tumor registry never involved patient consent because it is mandated by law. She indicated that there are areas a patient has no ability to consent for. She is aware that Susan Israel uses the example of the psychiatric issue, but she would want her doctors to have all her information and this issue is a discussion of privacy vs. confidentiality. Susan Israel indicated that she is referring to patient choice

and would like everyone to be clear on each individual case. Tim Pletcher added that this is why they are using the use case approach. For example, each hospital or lab, as a legal entity, is making the decision to send data to the tumor registry and they are managing that consent. The HIE acts as a pass through in that case.

Rachel Rudnick said that this is no different than how HHS talks about cloud services provider. The vendor is creating the mechanism for the transfer, as opposed to serving as a repository or acting as holder of the information. Furthermore, it is up to the entity to make the decision about where to send this data. Tim Pletcher replied yes. However, he indicated there may come a situation where the HIE creates a longitudinal medical record use case. When this use case is created, there will be special rules specific to this use case and special patient consent. The community would define these rules, but Tim Pletcher indicated they would start with the network-of-networks side of the continuum.

Rachel Rudnik asked if specific use cases have been identified by the HIE. Tim Pletcher indicated that there have been a handful of use cases identified and prioritized, however it is up to this group to define what gets done with respect to policy. Rachel Rudnik believed in order to best use the skills and knowledge of the group, it would be good to know which use cases are actively under consideration. It is hard to say what this group's thoughts and decisions are going to be on a theoretical basis. Tim Pletcher agreed.

Tim Pletcher discussed the idea of pushing data to multiple endpoints. In this particular use case, the HIE has a list of all providers associated with the patient. The HIE is making the decision to route information to those providers. It is similar to the HIPAA chain, but at this point, the HIE is making a routing decision to notify multiple providers. Susan Israel asked if this will fall under the HIPAA TPO model or if it would include additional patient consent. Tim Pletcher indicated, generally, they will start with the HIPAA TPO model but will include additional requirements as specified under law.

Michael Matthews indicated that alerts were not part of the initial uses case being considered for implementation by the HIE. Once the group discusses policy development, they can address the overall structure and processes for future use cases such as alerts, genetics, and behavioral health data. He indicated that the group should review the policy needed to support the initial use cases first. He asked if this approach worked and no one disagreed.

Tim Pletcher indicated that pushing data is less complicated than pulling data. This is because there are other issues to address such as confidence in patient matching, where to get data from, and appropriate release of information from covered entities.

Nic Scibelli asked if this is what the CareQuality network does and, if so, how do they address these issues. Tim Pletcher indicated that this is a great question and it is not 100% spelled out. When people are exchanging data from Epic to Epic, there are some things in place but it not quite as visible. In the eHealth Exchange, they have some defined standards for where to insert the proof of consent. To Tim Pletcher's knowledge, this is not something shared directly with the patient. He asked Michael Matthews if anything is shared with the patient directly.

Michael Matthews indicated that there is nothing in the eHealth Exchange that is available to the patient. The Data Use and Reciprocal Support Agreement (DURSA) is the foundational trust agreement that enables participants to share data with one another. Through a SAML assertion, the entity is indicating that they have the right to ask for and receive this data. In the case of the eHealth Exchange, the policy of each Participant has to be respected by the other Participants with whom data is exchanged. TECCA may impact the "rules of the road" at some point in the future.

Lisa Moon indicated that this is a policy framework and there is no central network technology in place today. All of the controls and assurances of the policy are pushed out to the users in the periphery (the providers), which makes it different than the network they are describing. Nic Scibelli understood the Trust Framework

but was not very clear on how to apply what Lisa Moon mentioned. Tim Pletcher indicated that they are working on more specificity and granularity through each use case.

Tim Pletcher indicated that each use case defines primary and permissible uses. The “fine print” exists in these sections. These are the areas that people want to pay attention to and ensure there is adequate conversation.

Tim Pletcher indicated that they are advocating to focus the initial conversations on the primary data flows of HIPAA and public health. These are the easiest initial use cases to address; they will anchor the conversation on what is already permissible under national laws relative to HIPAA and then public health takes on a state “flavor.” By starting with HIPAA, nothing precludes the group from building up to identified IRB research studies in the future.

Tim Pletcher explained, within HIPAA, there is a concept that covered entities with relationships in common may share individually identifiable health information. This is a well understood definition for treatment, payment and operations. Covered entities include providers, health care organizations, health care clearinghouses and health plans. Tim Pletcher indicated that the question then becomes how to know which covered entities have patients in common.

Susan Israel clarified that a patient cannot opt-out of the health information exchange. The health information exchange will transfer data between covered entities without patient consent. Tim Pletcher responded yes.

Carol Robinson indicated that the Design Group has been charged with making recommendations to the HIT Advisory Council and HITO about future consent policies for the statewide HIE entity. She clarified that the proposal being presented by Velatura is a strawman to determine if there is a baseline policy for consent that the group can find consensus on, and went on to say there would be a methodology to document dissenting opinions if those occur. Carol Robinson also stated that state agency staff and the consultants facilitating the Design Group are not telling this group what the recommendations will be or should be, but rather they are providing a proposal for the group’s consideration. If the majority of Design Group members concur with some or all of the use cases that are presented in coming meetings as not requiring additional consent beyond HIPAA requirements, those use cases will move forward as recommendations. In upcoming meetings the group will deliberate on how consent policies and procedures for those use cases where the boundaries of HIPAA are insufficient and more explicit consent for data use or data sharing should be required.

Susan Israel asked the group if they will give opinions on whether they are agreeing that the HIE will use data without consent. She wanted transparency for the public to see where data is going with, or without, consent.

Carol Robinson indicated the decision for recommendations will be made by the members of the Design Group and that a tiered approach to setting requirements for consent based on the purpose and uses of health data is one approach for the group to consider. The goal of the Design Group is to recommend how to apply consent in the appropriate ways for the appropriate purposes. The first consideration is related to what is already being communicated via electronic fax, phone, or electronic health record. The discussion is currently focused on use cases for data that is already moving under current law, and the overarching goals for statewide health information exchange are to improve health and healthcare delivery, while also not adding to provider burden of using technology.

Rachel Rudnick indicated that one thing they have not discussed is notice. In framing this conversation, pieces of consent may not be an option, but notice is. From UConn Health’s perspective, they would share this information with an HIE, but they would have notice of privacy practices that explain why they participate. If a patient did not want their information shared, they could receive health care somewhere else.

<p>Tim Pletcher said they are proposing a model where that notice is being done at the hospital, provider, and covered entity level. That responsibility lives there.</p> <p>Rachel Rudnik would like to ensure that message is very clear. Tim Pletcher agreed. He indicated that the starting place is HIPAA and it fully leverages those notices. Rachel Rudnik clarified that it is not just HIPAA; it should also take into account each hospital's position.</p> <p>Susan Israel indicated that some covered entities allow sensitive data to be combined with rest of the record. From her perspective, it seemed like some covered entities are trying to get around regulations, so it is easier to take care of people.</p> <p>Tim Pletcher indicated that this is why the entity will be responsible. The entity would not send data unless they have appropriate consent in place to do so. Rachel Rudnik added, as a business associate, the HIE will take on as much liability as the covered entity. She believed that they need to be clearer, as providers will participate for various reasons and not everyone will be viewing this from the patient perspective.</p>		
<p><b>5. Wrap-up and meeting Adjournment</b></p>	<p><b>Michael Matthews</b></p>	<p><b>2:00 PM</b></p>
<p>Michael Matthews thought this was a very productive and engaging conversation. He thanked the Velatura team. They will pick up the conversation at the next meeting.</p>		

**Upcoming Meeting Schedule:** June 4, 2019; June 18, 2019; July 9, 2019; July 23, 2019